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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,349	03/26/2004	Jerome Asius	22114-00001-US1	7560

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EXAMINER
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PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/809,349

Applicant(s)

ASIUS ET AL.

Examiner

Paul B. Prebilic

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 10-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date various.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

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With regard to the status inquiry filed September 27, 2005, it should have been responded to by customer support. The Office regrets if this did not happen. The following is a first action on the merits.

***Information Disclosure Statement***

The information disclosure statement filed April 29, 2005 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. Particularly, the Japanese patent JP 8507713 was cited but no translation of at least the relevant parts thereof was provided. Therefore, it has been placed in the application file, but the information referred to therein has not been considered.

The information disclosure statement filed June 25, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Some of these documents could not be found in the parent file so they could not be considered. However, the Examiner was able to find some of these documents via a patent number search so they have been cited on the enclosed PTO-892.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 13-17, 20-23, and 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claims 13-17, in claim 13, lines 1-2, the language "said hydrogel precursor comprises" contradicts base claim 10 where the precursor is limited to "consisting essentially of materials." Claims 14 to 17 are indefinite because they depend upon claim 13.

With regard to claims 20 to 22, it is unclear what form the implant is in, whether hydrated or not, because the water is not clearly claimed as mixed with the product of claim 10. For this reason, it is unclear which interpretation is intended by the claims. Claims 21 and 22 depend from claim 20, and therefore, contain the same language by incorporation.

On line 3 of claims 23 and 27, it is unclear what element, the gel or the microparticles, are being modified to be of materials of non-animal origin. The Examiner suggests inserting "; said gel" after "gel" in order to overcome this objection, if that is what was intended.

With regard to claims 25 and 26, the preamble of "[t]he kit of claim 23" renders the claim scope unclear because claim 23 is drawn to a "product." It is unclear if the preamble is attempting to broaden or modify the scope of claim 23. It may be that claims 25 and 26 were intended to depend upon claim 24 instead.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21 and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14 and 2, respectively, of U.S. Patent No. 6,716,251. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are read on by the patented claims such that they would be "anticipated" thereby if the patented claims were treated as prior art. For this reason, the present claims are considered clearly obvious over the patented claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sander et al (US 5,356,629) in view of Supersaxo et al (US 5,470,582). Sander meets the claim language where the microparticles of polymers of non-animal origin are disclosed on column 3, line 48 et seq. of Sander, the hydrogel as claimed is the gel of the matrix; see column 2, lines 35-56 and the dried state is suggested by the "prior to being wetted" state; see column 3, lines 38-47. However, Sander fails to clearly disclose that the matrix is completely dry as suggested by the freeze-dried state. Supersaxo, however, teaches that it was known to freeze dry or dry similar materials in order to stabilize them for storage; see column 2, lines 19-26 and column 4, lines 40-46. Therefore, it is the Examiner's position that it would have been obvious to freeze-dry the Sander matrix for storage or for the same reasons that Supersaxo does the same.

With regard to claim 11, since the same material as claimed is disclosed by Sander, the Examiner asserts that it inherently and necessarily has the same bioresorption rate. Furthermore, it is noted that the range does not clearly have a lower limit because within about one to about three years can be interpreted as meaning the same as up to about three years.

With regard to claim 15, the Applicants are directed to column 2, lines 57-66 of Sander.

With regard to claim 16, the Applicants are directed to the paragraph bridging columns 2 and 3 of Sander.

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With regard to claims 17 to 19, Supersaxo teaches the concept of including cryoprotectants and surfactants where mannitol and a surfactant is utilized; see column 4, lines 47-54. Therefore, it is the Examiner's position that it would have been obvious to utilize the same in Sander for the same reasons that Supersaxo utilizes the same.

Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sander and Supersaxo as applied to claims 10-23 above, and further in view of Scopelianos et al (US 5,599,852). Sander as modified by Supersaxo fails to disclose the use of a kit, vial, or syringe as claimed. However, Scopelianos teaches that it was known to the art to include a kit with a syringe; see the abstract, column 1, lines 48-57, column 8, line 24 et seq., and the claims. Therefore, it is the Examiner's position that it would have been *prima facie* obvious to utilize a kit with a syringe and vial to store the product for the long term, as suggested by Supersaxo, and to make it easier to the product.

### **Conclusion**

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Preblich whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Paul Prebilio  
Primary Examiner  
Art Unit 3738